

Claims

1. Enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity, which comprise (1) tamsulosin or its salt and at least (2) an enterosoluble substance, and when necessary contain (3) a water-insoluble substance, and which have the following characteristics:

- 1) A particle diameter of approximately 5 to 250 μm
- 2) When dissolution tests are performed on tablets that disintegrate in the buccal cavity containing these particles by dissolution testing methods cited in the Japanese Pharmacopoeia,
 - a) the dissolution rate of tamsulosin or its salt at a pH of 1.2 two hours after starting tests is 25% or less
 - b) the time when 50% of the tamsulosin or its salt has dissolved at a pH of 6.8 is 0.5 to 5 hours.

2. The enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity according to claim 1, wherein the enterosoluble substance is an enterosoluble polymer and/or higher fatty acid.

3. The enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity according to claim 2, wherein the water-insoluble substance is a water-insoluble polymer and/or wax.

4. The enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity according to claim 3, characterized in that dissolution of the tamsulosin or its salt is controlled by a controlling film and/or matrix.

5. The enteric sustained-release fine particles according to claim 4, wherein a layer or matrix containing an enterosoluble base is the layer that touches the dissolution fluid or the outermost layer, and the layer containing the water-insoluble substance is farther inside the particles than at least the layer of the enterosoluble base.

6. A method of producing enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity, which comprise (1) tamsulosin or its salt and at least (2) an enterosoluble substance, and when necessary contain (3) a water-insoluble substance, and which have the following characteristics:

- 1) A particle diameter of approximately 5 to 250 μm
- 2) When dissolution tests are performed on tablets that disintegrate in the buccal cavity containing these particles by dissolution testing methods cited in the Japanese Pharmacopoeia,
 - a) the dissolution rate of tamsulosin or its salt at a pH of 1.2 two hours after starting tests is 25% or less
 - b) the time when 50% of the tamsulosin or its salt has dissolved at a pH of 6.8 is 0.5 to 5 hours.